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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,478	02/11/2005	Dodda Mohan Rao	S2096/20001	6950

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EXAMINER
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LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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05/22/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,478	<b>Applicant(s)</b> MOHAN RAO ET AL.	
	<b>Examiner</b> SUN JAE Y. LOEWE	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Claims 1 and 2 are pending in the instant application.

***Response to Amendment***

2. The amendments to the claims filed on February 4, 2008 have been fully considered. The amendments successfully overcome the following grounds of rejection, which are hereby withdrawn: a) 35 USC 112 1<sup>st</sup> paragraph (enablement) rejection; b) 35 USC 102 rejections of claim 24 (office action dated November 8, 2007; Sections 9 and 10). The amendments do not overcome the remaining outstanding grounds of rejection set forth in the previous office action (November 8, 2007; Sections 5-8).

3. Applicant's remarks submitted on February 4, 2008 have been fully considered, however, they are not persuasive in overcoming the remaining outstanding grounds of rejection set forth in the previous office action (November 8, 2007; Sections 5-8). Responses to Applicant's remarks are provided below, Sections 4 and 5.

***Claim Rejections - 35 USC § 102***

4. Below are responses to Applicant's remarks concerning the grounds of rejection over Barbachyn et al., Meng et al. and Pearlman et al.

Applicant has rebutted the rejection by providing IR data for the prior art solid form of linezolid disclosed by the three references. It is maintained herein that IR data is not sufficient to unambiguously show that the cited prior art solid forms are indeed different from the instantly claimed invention. Applicant is respectfully directed to the reference of Brittain et al. (pg. 229),

which provides for the current state of the art in the identification of polymorphism, excerpts below:

“...nonequivalent x-ray powder diffraction pattern is observed for each suspected polymorphic variation. All other methodologies must be considered as sources of supporting and ancillary information; they cannot be taken as definitive proof for the existence of polymorphism by themselves alone.”

Applicant is further referred to the discussion below, Section 5.

The 35 USC 102 rejection of claims 1 and 2 over the references of Barbachyn et al., Meng et al. and Pearlman et al. are maintained and hereby made FINAL.

5. Below is a response to Applicant's remarks concerning the ground of rejection over Perrault et al.

Applicant has rebutted the rejection by providing XRD and IR data for the solid form disclosed by Perrault et al. The response is not persuasive for the following reasons.

First, claim 1 refers to a crystalline form of linezolid with peaks "at about" the 2theta values provided. Furthermore, the claim does not exclude the presence of other peaks in addition to those claimed. Therefore, Applicant's reference to the XRD peaks "

7.14, 9.58, 13.91, 14.27, 16.28, 16.83, 17.72, 19.44, 19.96, 21.63, 22.42, 22.87, 23.54, 24.20,

26.66, 27.01 and 27.77 degrees. " does not distinguish the prior art form as being different from the form instantly claimed. Rather, the prior art form as identified by the above noted XRD pattern is encompassed by the instant claims.

Furthermore, the presence of distinct XRD data may not be sufficient to establish a difference in the crystalline forms. For instance, it is well known in the art that purity affects

spectral/XRD data. Thus, absent a purity comparison, distinct differences in XRD/spectral data alone cannot conclusively as being a result of different polymorphic forms.

The 35 USC 102 rejection of claims 1 and 2 over the reference of Perrault et al. is maintained and hereby made FINAL.

### ***Conclusion***

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./  
5-14-2008

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626